

## **REMARKS**

### **Request for clarification:**

In the Disposition of Claims, the Action lists claims 38-62 as pending in the case with claims 38-49 and claims 52-62 withdrawn from consideration. Claims 49-62 have been listed as rejected.

Under Status of Claims, 49-62 are stated as being examined in the case.

Applicants request confirmation that claims 52-62 were not withdrawn from consideration.

### **Restriction/Election:**

Applicants elect claims 50-62 for examination. Applicants cancel claims 38-49, but reserve the right to refile the non-elected claims in a divisional application. Applicants disagree with reasons for the restriction and with the objection to claim 49; however, in the interest of expediting prosecution have complied with making the election.

### **Objection to Claim 49:**

The amended claims are directed to the elected invention. This objection is moot due to the cancellation of claim 49. Elected claims have been amended to remove dependency on canceled claim 49.

## **REJECTION UNDER 35 USC §102, SECOND PARAGRAPH**

Claims 50-62 are rejected under 35 USC §112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

In an effort to provide additional clarity to the claims, Applicants have amended claims 50 and 51 in accordance with the examiner's helpful suggestions; however, Applicants do not agree with the rejection of claim 53.

Regardless of the examiner's definition of "trait", Applicants have clearly described "A gene that results in an altered plant phenotype is any gene whose expression leads to the plant exhibiting a trait or trait that would distinguish it from a plant of the same species not expressing the gene." See [0037]. The particular "traits" listed include "...different growth habit, altered flower or fruit color or quality, premature or late flowering, increased or decreased yield, mortality, disease susceptibility, altered production of secondary metabolites, or an altered crop quality such as taste or appearance." Applicants submit that they are entitled to use the term "trait" as they have defined it in the specification.

Trait is a "distinct alternative form of a characteristic" as defined in the Glossary in *Understanding Genetics*, by N.V. Rothwell (Wiley-Liss, New York, 1993, page 623). Characteristic is defined as "A general attribute of an organism." (*Id.* at 611). An attribute is defined in Webster as an inherent characteristic or a word ascribing a quality (*Ninth New Collegiate Dictionary*, 1989).

Accordingly, Applicants believe they are entitled to use the "traits" described in the specification; however, should the examiner object on grounds other than §112, second paragraph, Applicants request specific reasons.

#### **REJECTION UNDER 35 USC § 112, FIRST PARAGRAPH**

Claims 50-52 are rejected under 35 U.S.C. §112, first paragraph as lacking enablement. The Examiner refers to the rejections as those set forth in the paper mailed June 1, 2004. In reviewing the June 1, 2004 rejection, the Examiner asserts finding no written description for "FLP, Cre, R, Gin, PIV, FlmB, C31, KW, SSV, IS1110IS492, TnpX, AG, AGL5, Bcp1, LAT52, PLENA, SIM, avrRp2 and alc". The Examiner invited applicants to point out in the specification where the terms are found.

In response, as stated in Applicants' paper mailed October 1, 2004, "As requested by the Examiner, Applicants respectfully point out that written description is provided for the

recombinases FLP, Cre, R, Gin, PIV, FimB, C31, KW, SSV, IS1110/S492, TnpX, in the specification on page 27, [0058], lines 4-5 and for the promoters AG, AGL5, Bcp1, LAT52, PLENA, SIM, avrRp2 and alc at [0059], line 6. Applicants submit that this rejection was overcome and is improperly repeated. Additionally, the currently pending claims do not list additional recombinases, only inducible promoters (AG, AGL5, Bcp1, LAT52, PLENA, SIM, avrRp2 and alc). One skilled in the art would recognize that these named promoters could be used as promoters with the described constructs and would have a reasonable expectation that these promoters would also work. A written description can be satisfied by words and is measured at the time of invention, not at time of patenting, to show that the applicant possesses the invention later claimed. In fact, the written description of the additional inducible promoters does allow the skilled artisan to make and use the claimed invention because applicants showed that the invention is operable using an inducible promoter.

The rejection in the Office Action of June 1, 2004 further asserts that the claims are overly broad and that the "Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden."

In view of the working examples provided by Dr. Li, the exemplary constructs, and the claims as currently amended, Applicants strongly disagree with the examiner's assertions, particularly that the claims do not cover a "virtually ad infinitum of possibilities". Dr. Li has demonstrated virtually 100% removal of the transgene, and as is well recognized, claims do not necessarily preclude optimization and some experimentation.

#### **APPLICANTS' REQUEST FOR CLARIFICATION AND RECONSIDERATION**

Applicants respectfully request the Examiner to further clarify the basis of the written description and enablement rejections. In an effort to accommodate Examiner's rejections based on lack of clarity, Applicants have incorporated the Examiner's suggestions and have employed the language found in section [0072] of the specification to further clarify the Examiner's concerns over the use of the term "excision site".

Applicants respectfully remind the Examiner that in the Office Action mailed June 1, 2004, enablement was acknowledged for "...a method comprising introducing a gene, said heterologous DNA flanked 3' by a Lox/FRT molecular hybrid recombinase recognition sequence, and flanked 5' by DNA encoding FLP recombinase operable linked to a Bcp promoter that is downstream of a second Lox/FRT molecular hybrid recombinase recognition sequence, said Lox/FRT sequences being in direction repeat orientation, does not reasonably provide enablement for the broad scope of the claims." (page 9 of the office action).

Applicants further refer to the Declaration of Dr. Yi Li, submitted previously in response to the Action's enablement rejection based on lack of "working" examples. Attention is drawn to item 3, of Dr. Li's declaration, where it is stated that he has demonstrated the excision from a transgenic plant "employing the methods disclosed in the referenced patent application." The methods are disclosed in the specification, see Example 1, et seq. beginning on page 32. The constructs are shown in the figures, there is guidance in [0039]-[0044] for example.

The point is that in view of the skill and knowledge in the art at the time the application was filed on July 27, 2001, there is ample written description to show that applicants had possession of the invention and there is ample guidance to enable those of skill in the art to make and use the invention without undue experimentation. Dr. Li's declaration demonstrates this. His data show working examples, which the skilled artisan could readily have duplicated based on the specification as filed, using the description, the specifics in the Examples and looking to the Figures for making the disclosed constructs. The experimental details, such as constructing the cassettes, are well-known techniques. By describing the constructs, by disclosing specific recombinases, it would be merely routine to provide working examples, as were provided by the data submitted in Dr. Li's declaration.

#### **REQUEST FOR FURTHER CONSIDERATION**

Applicants recognize that this response is filed after Final Office Action. In view of the long prosecution and efforts of the Applicants to respond to the Examiner's concerns, Applicants request reconsideration of the currently amended claims. Amendments are made for purposes of

*Applicants: Yi Li, et al.*  
*Serial No. 09/916,780*

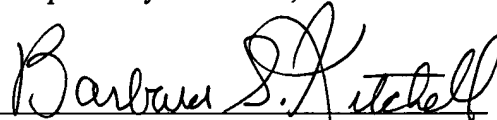
clarity, not to introduce substantive changes or to introduce new matter that would impose additional burden on the Examiner.

Conclusion

It is believed that the claims are in condition for allowance and reconsideration is respectfully requested. Should the Examiner have any questions, comments or suggestions, the undersigned requests a telephone conference at the number provided.

Date: 10 Feb. 2005

Respectfully submitted,



Barbara S. Kitchell, Reg. No. 33,928

Edwards & Angell LLP

P.O. Box 55874

Boston, MA 02205

(203) 353-6848

Attorneys for Applicant

Customer No. 21874